UNITED STATES DISTRICT COURT

DISTRICT OF SOUTH DAKOTA

WESTERN DIVISION

CRAIG KENDALL, Plaintiff, vs. BAUSCH & LOMB INCORPORATED and LASER VISION CENTERS, INC., Defendants.	)	CIV. 05-5066-JLV ORDER ON MOTION TO ADMIT EVIDENCE OF PRIOR INCIDENTS OF DLK

INTRODUCTION

Plaintiff filed a motion seeking the admissibility of prior incidents of DLK[1] from blade lot #517984. (Docket 273). This motion was filed in response to the court's earlier directions in its memorandum opinion and order.[2] (Docket 252 at pp. 12-14; Docket 271). The motion was fully briefed and is now ripe for resolution. The motion to admit evidence of prior incidents of DLK is granted in part and denied in part.

[1]"DLK [diffuse lamellar keratitis] is an inflammatory condition that sometimes occurs following LASIK surgery . . . [and] manifests itself in the interface of the corneal flap." (Docket 183, #22). Throughout the balance of this decision, DLK will refer to post-operative DLK.

[2]Chief Judge Karen E. Schreier presided over this case until it was assigned to the undersigned district judge.

DISCUSSION

"The proponent bears the burden of establishing that the 'facts and circumstances of the other incident' are substantially similar to this case." Sheesley v. Cessna Aircraft Company, Civ. Nos. 02-4185-KES, 03-5011-KES, 03-5063-KES, 2006 WL 3042793 *11 (D.S.D. 2006) (citing Drabik v. Stanley-Bostitch, Inc., 997 F.2d 496, 508 (8th Cir. 1993).

"Although evidence of prior accidents may be admissible to prove notice on the part of a defendant, any such accidents admitted must be 'sufficiently similar in time, place or circumstances to be probative.' " First Security Bank v. Union Pacific Railroad Co., 152 F.3d 877, 879 (8th Cir. 1998) (internal quotation marks omitted). "Evidence of other accidents may be relevant to the defendant's ability to correct known defects, the magnitude of the danger, the lack of safety for intended uses, or causation. It can also prove notice of the existence of defects." Id. "For other accident evidence to be admissible, the proponent of the evidence must show that the facts and circumstances of the other incident are substantially similar to the case at bar." Id. at 880. In other words, "for prior accidents to be relevant to establish notice to defendant, accidents 'must have occurred under circumstances substantially similar.' " Id. (citing Lewy v. Remington Arms Co., Inc., 836 F.2d 1104, 1109 (8th Cir. 1988)). "The admissibility of other accident evidence is within the

discretion of the trial court and its decisions will not be disturbed unless there is a clear and prejudicial abuse of discretion." Id.

In Lewy, the Court of Appeals for the Eighth Circuit evaluated the propriety of admitting business records maintained by Remington. Plaintiffs presented evidence of records of customer complaints and Remington's Gun Examination Reports (GERs). Lewy, 836 F.2d at 1108. Those complaints and GERs were for a Model 700 rifle, alleged to be similar to the Model 700 rifle which discharged in that case. Id.

"In order to be admissible a proper foundation must be laid showing that the other incidents involving a Model 700 discharging on release of the safety occurred under circumstances substantially similar to the circumstances surrounding the discharge of the Lewy rifle." Id. "Each report contains a statement of the customer's complaint and the circumstances relating to the alleged [firing on release of the safety]. These GERs, as well as the other evidence supporting them, sufficiently established the foundation for the admission of the M700 evidence." Id. Based on these substantially similar circumstances, the Eighth Circuit ruled the plaintiffs had "laid an adequate foundation for admission of the related incidents involving the Model 700." Id.

The Lewy court concluded the prior incidents evidence was relevant to a number of contested trial issues. "First, it was relevant to whether Remington

had notice. Notice was a hotly contested issue and was an important element of the Lewy's failure to warn theory of the case." Id. "Second, the evidence was relevant to show causation. Under Fed. R. Evid. 401, evidence of similar occurrences might be relevant to the defendant's notice, magnitude of the danger involved, the defendant's ability to correct a known defect, the lack of safety for intended uses, . . . the standard of care, and causation." Id. (internal quotation marks omitted).

Plaintiff argues the prior incidents of DLK occurring during LASIK[3] surgery using a Bausch and Lomb Incorporated ("B&L") AccuGlide™ blade from the same lot as the blade used during plaintiff's surgery are probative because they show:

1. B&L had notice of the defects and danger;

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[3]"In a typical LASIK procedure, the patient is given an oral medication to relax him before the procedure. The patient is draped and the lashes of the eye or eyes are taped. The patient receives a topical anesthetic administered from a bottle that works through the entire cornea of the operated eye. The cornea is marked with dye from [a] reference marker. The surgeon uses a microkeratome, which is a small mechanical device with a bade, to cut a very thin, usually hinged flap of the corneal tissue. Once the flap is made, the surgeon removes the microkeratome and lifts the flap with an instrument, typically a cannula, forceps or spatula. The flap is folded out of the way and the exposed stromal bed is wiped with a sponge or Weck cell. The surgeon uses laser energy to ablate, or remove, corneal tissue. The flap is replaced, the interface is copiously irrigated with balanced salt solution from a cannula, and the flap is wiped and stretched with a sponge or Weck. Medicinal drops are administered, usually topical anesthetic, antibiotics and anti-inflammatory." (Docket 183, #7).

2. B&L could have corrected the defect: and

3. B&L determined the blades from lot #517984 were the only common element that could have caused the DLK.

(Docket 277, p. 1). Plaintiff submits those incidents of DLK are substantially similar to the facts in his case based on the following evidence: (1) "admissions of Bausch and Lomb Incorporated ("B&L"), in the form of employee testimony and B&L business records"; and (2) "affidavits and testimony of the doctors who performed the LASIK procedures that resulted in the prior incidents of DLK." Id.

Plaintiff represents he will "present[] the evidence of prior incidents of DLK through B&L's own records that have been kept in the regular course of its business which are admissible under Rule 803(6)." (Docket 279, p. 2). At trial, to avoid B&L's hearsay objection, plaintiff indicates he will not present the actual customer complaints.[4] Id. Rather, plaintiff "intends to introduce B&L corporate memorandums, reports, charts and timelines that the company produced regarding DLK incidents related to lot #517984." Id. at p. 3. Plaintiff argues these prior complaints are admissible to allow the jury to determine how much notice B&L had of DLK occurrences prior to the date of plaintiff's surgery. (Docket 277, p. 8).

[4]These complaints were received from physicians or clinical staff reporting conditions of their patients. For further reference, these physicians will be identified as the "customer," as opposed to the patient who is the ultimate recipient of the use of the surgical blade.

B&L Admissions and Employee Testimony

B&L's responses to plaintiff's second requests for admission (Docket 273-2) disclose information relevant to the prior incidents under Fed. R. Civ. P. 36(b). Rule 36(b) provides that "[a] matter admitted under this rule is conclusively established . . . ." Those admissions are summarized, as follows:

Complaints reporting the onset of DLK after LASIK surgery with a B&L AccuGlide™ blade from Lot #517984:

1. On November 18, 2002, B&L received a complaint of 2 patients in Dallas, Texas. (Docket 273-2, #1).

2. On November 22, 2002, B&L received a complaint from LCA Vision/Albany [New York] of 17 patients. Id. at #2.

3. On November 25, 2002, B&L received a complaint of 15 patients of Dr. Mark Johnston [Omaha, Nebraska]. Id. at #3.

4. On November 29, 2002, B&L received a complaint from Advanced Laser Vision [Houston, Texas] of 4 patients. Id. at #4.

5. On December 9, 2002, B&L received a complaint of 20 patients [in Baton Rouge, Louisiana]. Id. at #8.

6. On December 9, 2002, B&L received a complaint of 9 patients [in Anchorage, Alaska]. Id. at #9.

7. On December 10, 2002, B&L received a complaint [from American Laser Specialists in Stow, Ohio] of 50 patients. Id. at #10.

8. On December 10, 2002, B&L received a complaint [from LVCI (Laser Vision Centers, Inc.), of St. Louis, Missouri] of 78 patients. Id. at #11.

9. Between November 10, 2002, and December 10, 2002, B&L received a total of 195 complaints. Id. at #12.

B&L internal consideration of the DLK complaints:

1. On December 2, 2002, B&L employee Tom Brennan thought B&L needed to have a containment meeting.[5] Id. at #5.

2. On December 2, 2002, Mr. Brennan indicated he would "make sure that we quarantine remaining inventory of this lot, if any exists, pending the meeting." Id. at #7.

3. On December 2, 2002, B&L quarantined blades from that lot which had not already been shipped to customers. Id. at #6.

4. B&L withdrew the remaining blades from that lot from the market after it received reports indicating approximately 150 people developed post-operative DLK after LASIK surgery with blades from that lot. Id. at #13.

Depositions of B&L employees disclose additional information relevant to the issues of notice and failure to warn of potential harm. Julie Moore, as a B&L administrator in product surveillance, was responsible for receiving customer complaints about B&L products, including the AccuGlide™ blade from lot #517984. (Docket 277-1, pp. 2-3). Those complaints would be entered into the B&L system, called a "Complaint Master." Id. at p. 3. Ms. Moore and her staff would "evaluate the complaint for reportability to the FDA

[5]"The purpose of the containment meeting is to get a number of people together to discuss . . . all aspects of the containment of that product." (Docket 189-10, p. 2).

for adverse event reporting" using the "FDA guidelines for reportability to determine malfunctions or injuries." Id.

On November 25, 2002, Ms. Moore communicated with her superior about the lot #517984 AccuGlide™ complaints because there were a "couple of reports of DLK so closely together." Id. at p. 4. She identified these complaints as significant because they created a "potential for serious injury." Id.

Ms. Moore's report was e-mailed to Mr. Brennan and another employee who works for him. (Docket 277-2, p. 4). Her report identified three different customers, at three different sites, reporting 37 patient outbreaks of DLK with blade lot #517984. Id. at p. 2.

Mr. Brennan was the quality manager of the B&L St. Louis, Missouri, facility. Id. These complaints were a "Level 1" priority complaint, the highest priority complaint in the B&L system. Id. at p. 3. A "Level 1 complaint was a product complaint in which the complainant alleges patient injury may have occurred and the alleged injury may have been due to the product." Id. It may "also include anything that . . . could lead to or any complaint deemed by Bausch & Lomb to need special attention, such as a product that was not properly labeled, for example." Id.

Another report was e-mailed by Ms. Moore to Mr. Brennan on December 2, 2002, indicating a fourth customer report of 4 patients developing DLK

using the same lot blade. Id. Mr. Brennan acknowledges these were conditions, associated with this blade lot, which could lead to serious injury. Id. "It [was] now a reportable condition." Id. at p. 4. On December 5, 2002, Mr. Brennan was aware that another clinical site was reporting 10 cases of DLK after using blades from this lot. Id. at p. 5. B&L knew that DLK can pose a substantial risk of harm. Id. at p. 7.

B&L "did not set up a containment meeting until December 9, 2002, even though it was [Mr. Brennan's] regular practice to set up a containment meeting within 24 hours of notification of a potential problem." (Docket 252 at p. 4). Plaintiff Kendall's LASIK surgery was on December 10, 2002. (Docket 183, #2). His surgery was a "typical" LASIK procedure and unremarkable. (Docket 183, #16 and #17); see also footnote #3, supra. A recall of AccuGlide™ blades of lot #517984 was initiated by B&L on December 13, 2002. (Dockets 98-4 and 98–15). This was done by telefax and telephone. Id.

B&L identified no common elements in those prior surgeries where DLK developed, other than the blade lot. See deposition of Mr. Brennan (Docket 277-2, p. 6); deposition of Michael Santalucia, Vice President of Regulatory Affairs for Medical Devices (Docket 277-3, pp. 2 and 4); and deposition of Glenn Davies, Director of Regulatory Affairs (Docket 277-4, pp. 3). Mr. Davies is not blaming anything else for the DLK which developed. Id.

Affidavits and Depositions of Other Physicians

Plaintiff apparently seeks to introduce at trial the following testimony associated with the prior incidents issue, namely, the affidavits of Mark G. Ballif, M.D. (Docket 273-3), Mark E. Johnston, M.D. (Docket 273-4), Richard Phinney, M.D. (Docket 273-5), and David R. Hardten, M.D., FACS (Docket 273-6), and the deposition testimony of Jonathan Rosin, M.D. (Docket 273-7).

"Hearsay is a statement, other than one made by the declarant while testifying at the trial . . . , offered in evidence to prove the truth of the matter asserted." Fed. R. Evid. 801(c) (internal quotation marks omitted). "[T]he purpose of the hearsay rule [is] the exclusion of declarations whose veracity cannot be tested by cross-examination." United States v. Singer, 687 F.2d 1135, 1147 (8th Cir. 1982).

Admissions against a party-opponent under Rule 801(d)(2) are not hearsay. That section, as pertinent to this case, states as follows:

> Admission by party-opponent. The statement is offered against a party and is (A) the party's own statement, in either an individual or a representative capacity or (B) a statement of which the party has manifested an adoption or belief in its truth, or (C) a statement by a person authorized by the party to make a statement concerning the subject, or (D) a statement by the party's agent or servant concerning a matter within the scope of the agency or employment, made during the existence of the relationship, ...

Fed. R. Evid. 801(d)(2). Certain additional types of evidence are not excluded under the hearsay rule. Rule 803(6) identifies those items, pertinent to this case, as follows:

> (6) Records of Regularly Conducted Activity.--A memorandum, report, record, or data compilation, in any form, of acts, events, conditions, opinions, or diagnoses, made at or near the time by, or from information transmitted by, a person with knowledge, if kept in the course of a regularly conducted business activity, and if it was the regular practice of that business activity to make the memorandum, report, record or data compilation, all as shown by the testimony of the custodian or other qualified witness, ...

Fed. R. Evid. 803(6).

Complaints of Prior Incidents of DLK

The complaints of prior incidents of DLK are out-of-court statements. If the complaints received by B&L are offered to prove the truth of the matter asserted, that is, blades from the same lot as the blade used during plaintiff's LASIK surgery caused DLK, those complaints are hearsay. Rule 801(c). While those complaints may well have been made by professionals in the field of ophthalmology, each complaint, none-the-less, relies on the underlying veracity of the party reporting the occurrence of DLK. There seems to be little reason for a physician or clinic to falsely report a DLK occurrence in a relationship where the physician-customer relies on the quality of the B&L product. However, plaintiff's presentation of the complaints as proof of the truth of the matter asserted–the blade caused the DLK–is based on the veracity of the person making the complaint. With just the complaint documents, the "veracity cannot be tested by cross-examination." Singer, 687 F.2d at 1147. The complaints, if used for this purpose, constitute inadmissible hearsay. Rule 801(c).

B&L's admissions that it received these complaints from various identified sources does not change the application of Rule 801(c) to the information. These complaints are neither 801(d)(2) qualified admissions against a party-opponent, nor are they the type of business records contemplated by Rule 803(6). These customer complaints, simply because they had been received by B&L, "would . . . not tend to establish that the [blades] were ineffective, that the condition of the [blades] was dangerous, that [B&L] was negligent, or that a defective condition existed." Olson v. Ford Motor Company, 410 F. Supp. 2d 855, 862 (D.N.D. 2006).

Plaintiff also argues the customer complaints are admissible to show notice. (Docket 277, p. 1). "It is well-established that '[e]vidence of similar incidents may be relevant to prove the defendant's notice of defects, the defendant's ability to correct known defects, the magnitude of the danger, the product's lack of safety for intended uses, or causation.' " Olson, 410 F. Supp. 2d at 862 (citing Lovett ex rel. Lovett v. Union Pacific Railroad Company, 201 F.3d 1074, 1081 (8th Cir. 2000)). "Evidence that a manufacturer received customer complaints about a particular defect is admissible to show knowledge or notice on the part of the manufacturer." Id. See also Lewy, 836 F.2d at 1108-09 (customer complaints are relevant to the issue of whether the manufacturer had notice); First Security Bank, 152 F.3d at 879 (other accidents may be relevant to prove notice of the existence of defects).

B&L objects to the admission of the complaints because they were not "sufficiently similar to indicate that the complaint is reliable proof that the blade caused the patient's DLK." (Docket 278, p. 9). This is an inappropriate blending of the hearsay rule and the standard for consideration of other incidents. The "sufficiently similar" standard does not require the court to determine the other incidents provide "reliable proof that the blade caused the patient's DLK." Rather, the court is to determine the similarity of events and then allow the jury to decide whether those other events were reliable proof of notice or causation. First Security Bank, 152 F.3d at 877 and Lewy, 836 F.2d at 1104.

" 'Relevant evidence' means evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence." Fed. R. Evid. 401. Notice by B&L of other similar complaints is relevant to the issue of whether B&L had sufficient information upon which to react before plaintiff was subjected to the potential risk of a surgery which may, or may not, involve serious injury. First Security Bank, 152 F.3d at 879; Lewy, 836 F.2d at 1108.

From the admissions by B&L and the testimony of its employees, it is clear the complaints of prior incidents of DLK are "substantially similar to the circumstances" associated with plaintiff's surgery. Lewy, 836 F.2d at 1108.

The prior incidents of DLK occurred in the time frame immediately preceding plaintiff's surgery using blades from the same lot, and DLK developed during the post-operative period. These incidents are "sufficiently similar in time, place or circumstances to be probative." First Security Bank, 152 F.3d at 879. The complaints of prior incidents of DLK made to B&L are relevant and admissible evidence of notice.[6]

Affidavits and Depositions of Other Physicians

"Under [Rule] 401, evidence of similar occurrences 'might be relevant to the defendant's notice, magnitude of the danger involved, the defendant's ability to correct a known defect, the lack of safety for intended uses, . . . the standard of care, and causation.' " Lewy, 836 F.2d at 1108 (citing Kehm v. Procter & Gamble Manufacturing Company, 724 F.2d 613, 625 (8th Cir. 1983)) (other citation omitted). See also Thomas v. Chrysler Corporation, 717 F.2d 1223, 1225 (8th Cir. 1983) ("Evidence of prior accidents may be relevant to demonstrate, amongst other things, the existence of a defect, notice to a defendant, or causation. . . . However, the accidents must be sufficiently similar in time, place or circumstances to be probative.") (internal citation and quotation marks omitted).

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[6]"[O]nce the evidence is admitted [B&L] remains free to argue to the jury that the evidence is not persuasive by pointing out the dissimilarities in the [prior incidents] and [plaintiff's surgery]." Lewy, 836 F.2d at 1108.

Plaintiff submitted three affidavits from physicians who have concluded their patients developed DLK from a AccuGlide™ blade from the same lot as the blade used in plaintiff's surgery. (Dockets 273-3, 273-4, and 273-5). These affidavits are out-of-court statements offered to prove the truth of the matter asserted. They are inadmissible hearsay under Rule 801(c). The court will not admit these affidavits as substantive evidence at trial. This ruling does not preclude these physicians, with proper foundation, from testifying at trial on the matters contained in their affidavits and being subject to the vigorous cross-examination contemplated by Rule 801(c). Singer, 687 F.2d at 1147.

Plaintiff's designated expert, Dr. Hardten, however, is allowed to consider the other physicians' affidavits as part of his evaluation and development of his opinions under Rule 703. The rule provides, in pertinent part, "[i]f of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject, the facts or data need not be admissible in evidence in order for the opinion or inference to be admitted. . . ." Fed. R. Evid. 703. But like the affidavits of the other physicians, Dr Hardten's affidavit is not admissible as substantive evidence under Rule 801(c).

The deposition testimony of Dr. Jonathan Rosin was an examination, under oath, taken by both parties under Fed. R. Civ. P. 32. (Docket 273-7). B&L's argument that Dr. Rosin's testimony is either not credible on the issue

of causation, or actually supports defendant's position on that issue, is not relevant to this present analysis. Credibility and impeachment are issues to be resolved by the jury at trial.

ORDER

Based on the above analysis, it is hereby

ORDERED that plaintiff's motion to admit complaints of prior incidents of DLK (diffuse lamellar keratitis) from blade lot #517984 (Docket 273) is granted in part and denied in part.

IT IS FURTHER ORDERED that the complaints of incidents of DLK received by Bausch & Lomb prior to the date of plaintiff's surgery are not admissible to prove the AccuGlide™ blade used in plaintiff's LASIK surgery was defective.

IT IS FURTHER ORDERED that the complaints of incidents of DLK received by Bausch & Lomb prior to the date of plaintiff's surgery are admissible for the purpose of proving notice to defendant Bausch & Lomb.

IT IS FURTHER ORDERED that the four affidavits of physicians, namely: Mark G. Ballif, M.D., Mark E. Johnston, M.D., Richard Phinney, M.D., and David R. Hardten, M.D., FACS, are inadmissible as substantive evidence at trial.

IT IS FURTHER ORDERED that, if proper foundation is presented at trial, the physicians identified by plaintiff, namely: Mark G. Ballif, M.D.,

Mark E. Johnston, M.D., Richard Phinney, M.D., and David R. Hardten, M.D., FACS, and Jonathan Rosin, M.D., will be permitted to testify regarding the surgeries they performed on other LASIK patients using an AccuGlide™ blade from the same lot as the blade used in plaintiff's surgery, and the development of post-operative DLK in other patients.

Dated March 9, 2011.

BY THE COURT:

/s/ *Jeffrey L. Viken*
JEFFREY L. VIKEN
UNITED STATES DISTRICT JUDGE